

§ 52.3

Health Care Policy and Research, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health, the Office of the Assistant Secretary for Health, the Substance Abuse and Mental Health Administration, and the Agency for Toxic Substances and Disease Registry.

Research means a systematic investigation, study or experiment designed to contribute to general knowledge relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanisms relating to, the biological functions, diseases, or related matters to be studied.

Secretary means the Secretary of HHS and any other officer or employee of the HHS to whom the authority involved may be delegated.

[61 FR 55105, Oct. 24, 1996]

§ 52.3 Who is eligible to apply for a grant?

(a) *Persons eligible.* Any individual, corporation, public or private institution or agency, or other legal entity shall be eligible for a grant award, except:

(1) An individual or entity which is otherwise ineligible for an award under applicable law or regulation;

(2) Federal agencies or institutions, unless specifically authorized by law to receive the grant; or

(3) Individuals, corporations, institutions, agencies, and other entities during the period they are debarred or suspended from eligibility for Federal financial assistance (see 45 CFR part 76).

(b) *Permissible activities within research projects.* Any project found by the Secretary to be a research project within the meaning of this part shall be eligible for a grant award. Eligible projects may consist of laboratory, clinical, population, field, statistical, basic, applied or other types of investigations, studies or experiments, or combinations thereof, and may either be limited to one, or a particular aspect of a problem or subject, or may consist of two or more related problems or subjects for concurrent or consecutive in-

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vestigation and involving multiple disciplines, facilities and resources.

(c) *Preferences.* In the award of grants for international research relating to the development and evaluation of vaccines and treatments for AIDS under section 2315 of the Act, preference shall be given to:

(1) Activities conducted by, or in cooperation with, the World Health Organization, and

(2) With respect to activities in the Western Hemisphere, activities conducted by, or in cooperation with, the Pan American Health Organization or the World Health Organization.

[61 FR 55105, Oct. 24, 1996]

§ 52.4 How to apply for a grant.

Each institution interested in applying for a grant under this part must submit an application at such time and in such form and manner as the Secretary may prescribe.

[61 FR 55105, Oct. 24, 1996]

§ 52.5 Evaluation and disposition of applications.

(a) *Evaluation.* All applications filed in accordance with § 52.4 shall be evaluated by the Secretary through such officers and employees and such experts or consultants engaged for this purpose as the Secretary determines are specially qualified in the areas of research involved in the project, including review by an appropriate National Advisory Council or other body as may be required by law. The Secretary's evaluation shall take into account among other pertinent factors the scientific merit and significance of the project, the competency of the proposed staff in relation to the type of research involved, the feasibility of the project, the likelihood of its producing meaningful results, the proposed project period, and the adequacy of the applicant's resources available for the project and the amount of grant funds necessary for completion, and in the case of applications for support of research in emergency medical services, special consideration shall be given to applications for grants for research relating to the delivery of emergency medical services in rural areas.

(b) *Disposition.* On the basis of the Secretary's evaluation of an application in accordance with paragraph (a) of this section and subject to approvals, recommendations or consultations by the appropriate National Advisory Council or other body as may be required by law, the Secretary will (1) approve, (2) defer because of either lack of funds or a need for further evaluation, or (3) disapprove support of the proposed project in whole or in part. With respect to approved projects, the Secretary will determine the project period (subject to extension as provided in § 52.7(c)) during which the project may be supported. Any deferral and disapproval of an application will not preclude its reconsideration or a re-application.

[45 FR 12240, Feb. 25, 1980; 45 FR 20096, Mar. 27, 1980]

§ 52.6 Grant awards.

(a) Within the limits of funds available for that purpose, the Secretary will award a grant to those applicants whose approved projects will in the Secretary's judgment best promote the purposes of the statute authorizing the grant and the regulations of this part. The date specified by the Secretary as the beginning of the project period shall be no later than 9 months following the date of any initial or new award statement unless the Secretary finds that because of the nature of a project or the grantee's particular circumstances earlier assurance of grant support is required to initiate the project. Any funds granted under this part shall be expended solely for the purposes for which the funds were granted in accordance with the approved application and budget, the regulations of this part, the terms and conditions of the award and the applicable cost principles prescribed in subpart Q of 45 CFR part 74.

(b) *Evaluation of unapproved drug treatments for AIDS.* Grants under section 2314 of the Act to support research relating to the evaluation of drug treatments for AIDS not approved by the Commissioner of Food and Drugs, shall be subject to appropriate scientific and ethical guidelines established by the Secretary for each project, pursuant to section 2314(c) of

the Act. In order to receive a grant, the applicant must agree to comply with those guidelines.

(c) *Notice of grant award.* (1) The notice of grant award specifies how long HHS intends to support the project without requiring the project to re-compete for funds. This period, called the project period, will usually be for 1-5 years.

(2) Generally, the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit an application at the time and in the form and manner as the Secretary may prescribe to have support continued for each subsequent year.

(3) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

(d) *Multiple or concurrent awards.* Whenever a research project involves a number of different but related problems, activities or disciplines which require evaluation by different groups, or whenever support for a project could be more effectively administered by separate handling of separate aspects of the project, the Secretary may evaluate, approve and make awards pursuant to two or more concurrent applications, each dealing with one or more specified aspects of the project.

(e) *Unobligated balances.* The Secretary may permit unobligated grant funds remaining in the grant account at the close of a budget period to be carried forward for obligation during a subsequent budget period, provided a continuation award is made for that period and the Secretary's written approval is obtained.

(f) *Award for continuation of project under new grantee.* The Secretary, upon application in accordance with the provisions of § 52.4 and without further action by a Council or other body, may make a grant to any institution or other person eligible under § 52.3 for continuation of a currently supported project for which a grant was previously made to another institution or person, provided the Secretary finds